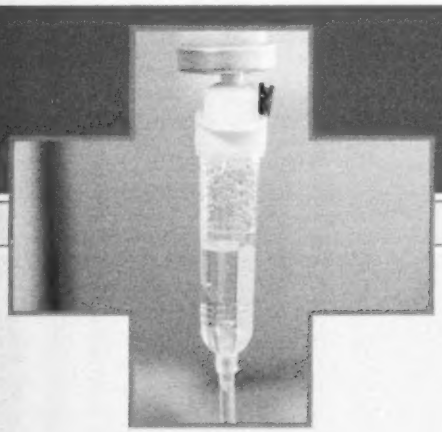
Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*



Health Product InfoWatch

August 2018

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REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Online: Adverse Reaction and Medical Device Problem Reporting
Telephone: 1-866-234-2345
Fax or mail: Form available online

SUBSCRIBE

To receive the Health Product InfoWatch and notifications of health product advisories electronically, subscribe to MedEffect™ e-Notice **or to** MedEffect™ Canada RSS feeds.

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

- Alunbrig (brigatinib)
- Avalide (irbesartan and hydrochlorothiazide)
- Avapro (irbesartan)
- EpiPen and EpiPen Jr (epinephrine)
- Imbruvica (ibrutinib)
- Remicade (infliximab)
- SGLT2 inhibitors
- Tactupump and Tactupump Forte (adapalene and benzoyl peroxide)
- Trombojet (sodium tetradecyl sulfate)
- Valsartan-containing drugs

Other

- Unauthorized health products

This monthly publication is intended primarily for healthcare professionals and includes information on pharmaceuticals, biologics, medical devices and natural health products. It provides a summary of key health product safety information published in the previous month by Health Canada, as well as a selection of new health product safety information meant to raise awareness. New information contained in this issue is not comprehensive but rather represents a selection of clinically relevant items warranting enhanced dissemination.

Canada

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of** health product advisories, type I recalls **as well as** summaries of completed safety reviews **published in July 2018 by Health Canada.

EpiPen and EpiPen Jr (epinephrine)

Information Update

Following Health Canada's most recent communication regarding a shortage of EpiPen (0.3 mg) and EpiPen Jr (0.15 mg) auto-injectors, Pfizer Canada has advised Health Canada that supply of EpiPen in the 0.3 mg format is expected to be very limited at pharmacies during the month of August. The company has also advised that, at this time, they continue to be able to supply EpiPen Jr (0.15 mg); however, the supply is limited and is being carefully managed at the national level.

Imbruvica (ibrutinib)

Summary Safety Review
Health Product InfoWatch

This safety review evaluated the risk of ventricular tachyarrhythmia associated with the use of Imbruvica (ibrutinib). Health Canada's review of the available information concluded that there may be a link. The Canadian product monograph for Imbruvica has been updated to include this risk. Health Canada also communicated this information to healthcare professionals.

Remicade (infliximab)

Summary Safety Review

This safety review evaluated the risk of linear IgA bullous dermatosis associated with the use of Remicade (infliximab). Health Canada's review of the available information concluded that there may be a link. The Canadian product monograph for Remicade has been updated to include this risk.

SGLT2 inhibitors

Summary Safety Review

This safety review evaluated the risk of acute and chronic pancreatitis associated with sodium-glucose cotransporter-2 (SGLT2) inhibitors (canagliflozin, dapagliflozin, and empagliflozin). Health Canada's review of the available information concluded that there may be a link between the use of SGLT2 inhibitors and acute pancreatitis. However there was limited evidence to suggest a link with chronic pancreatitis. Health Canada is working with the manufacturers to update the Canadian product monographs for SGLT2 inhibitors to include this risk.

Tromboject (sodium tetradecyl sulfate)

Health Professional Risk Communication

Vials of Tromboject 1% and 3% may contain visible and insoluble particles. Healthcare professionals are advised to use the product only when the benefits of Tromboject 1% and 3% therapy outweigh the risk of the treatment for medically necessary interventions or in conditions where there are no therapeutic alternatives for the patient. The product should be conserved only for medically necessary use due to the anticipated drug shortage of all Tromboject formats.

Unauthorized health products Advisory	Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.
Valsartan-containing drugs Advisory Information Update Drug Recall – Pro Doc Valsartan Drug Recall – Sandoz Valsartan Drug Recall – Sanis Valsartan Drug Recall – Sivem Valsartan Drug Recall – Teva Valsartan	Several drugs containing valsartan were recalled by their manufacturers (a list of affected products with DIN and lot number is provided in the advisory and information update). An impurity, N-nitrosodimethylamine (NDMA), a potential human carcinogen, was found in the valsartan used in these products. The valsartan was supplied by Zhejiang Huahai Pharmaceuticals.

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topics have been selected to raise awareness and, in some cases, to stimulate reporting of similar adverse reactions.

PRODUCT MONOGRAPH UPDATES

The following safety labelling updates, which were recently made to the Canadian product monograph, have been selected for your awareness. A complete list of safety labelling updates is available on Health Canada's *Product Monograph Brand Safety Updates*. ***Canadian product monographs can be accessed through Health Canada's*** *Drug Product Database*.

Avapro (irbesartan) and Avalide (irbesartan and hydrochlorothiazide)

The risk of **psoriasis exacerbation** has been included in the *Warnings and Precautions, Post-Market Adverse Reactions,* and *Consumer Information* sections of the Canadian product monographs for Avapro and Avalide.

Key messages for healthcare professionals:[1,2]

- The use of Avapro and Avalide in patients with psoriasis or a history of psoriasis should be carefully weighed as it may exacerbate psoriasis.

References

1. *Avalide (irbersartan and hydrochlorothiazide)* [product monograph]. Laval (QC): sanofi-aventis Canada Inc.; 2018.
2. *Avapro (irbesartan)* [product monograph]. Laval (QC): sanofi-aventis Canada Inc.; 2018.

Tactupump and Tactupump Forte (adapalene and benzoyl peroxide)

The use of Tactupump and Tactupump Forte is now **contraindicated** in pregnant women and in women planning a pregnancy. This information has been included in the *Contraindications* and *Warnings and Precautions* sections of the Canadian product monograph for Tactupump and Tactupump Forte.

Key messages for healthcare professionals:[1]

- Orally administered retinoids, including adapalene, have been associated with congenital abnormalities.
- Topical adapalene/benzoyl peroxide is contraindicated in pregnant women and in women planning a pregnancy because of the possibility of increased systemic exposure due to various factors, such as damaged skin barrier and excessive use.
- If the patient becomes pregnant while using these drugs, treatment should be discontinued.

Reference

1. *Tactupump and Tactupump Forte (adapalene and benzoyl peroxide)* [product monograph]. Thornhill (ON): Galderma Canada Inc.; 2018.

NOTICE OF MARKET AUTHORIZATION WITH CONDITIONS

A Notice of Compliance with Conditions (NOC/c) is a form of market authorization with conditions granted to a product on the basis of **promising** *evidence of clinical effectiveness following review of the submission by Health Canada. Communicating a NOC/c is intended to raise awareness on the details of the drug and the nature of authorization granted.*

Healthcare professionals are encouraged to report to Health Canada any adverse reactions suspected of being associated with marketed health products, including drugs authorized under the NOC/c policy.

The content of these notices reflects current information at the time of publication. Conditions associated with the NOC/c will remain until they have been fulfilled and authorized by Health Canada, in accordance with the NOC/c Policy. For the most up-to-date information, consult Health Canada's NOC database.

Alunbrig (brigatinib): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the Notice of Compliance with Conditions policy for Alunbrig (brigatinib) 30 mg, 90 mg and 180 mg tablets. Alunbrig is indicated as a monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non–small cell lung cancer who have progressed on or who were intolerant to an ALK inhibitor (crizotinib). Patients should be advised about the conditional market authorization for this indication.

For the complete prescribing information and information available for the patients/caregivers, please consult the Alunbrig Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Takeda Canada Web site or by contacting Takeda Canada Inc. at 1-866-295-4636. Contact the company for a copy of any references, attachments or enclosures.

HELPFUL LINKS

- MedEffect™ Canada
- Recalls and Safety Alerts Database
- New Safety Reviews
- Canada Vigilance Adverse Reaction Online Database
- Drug Product Database
- Medical Devices Active Licence Listing
- Licensed Natural Health Products Database
- The Drug and Health Product Register
- Drug Shortages Canada

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at HC.infowatch-infovigilance.SC@canada.ca

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Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

Due to time constraints relating to the production of this publication, information published may not reflect the most current information.

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